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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/727,868 | 12/04/2003 | Paul H. Norton | 8567-592U2 (P-0275) | . 7880 |
| PANITCH SCHWARZE BELISARIO & NADEL LLP ONE COMMERCE SQUARE 2005 MARKET STREET, SUITE 2200 PHILADELPHIA, PA 19103 | | | EXAMINER | |
| | | | GRAY, PHILLIP A | |
| | | | ART UNIT | PAPER NUMBER |
| THEREELI | | | 3767 | |
| | | | -0- | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 01/28/2008 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | , | A II AI N- | Applicanto | | | | |
|--|---|---|---|--|--|--|--|
| Office Action Comments | | Application No. | Applicant(s) | | | | |
| | | 10/727,868 | NORTON ET AL. | | | | |
| Omic | e Action Summary | Examiner | Art Unit | | | | |
| <u> </u> | | Phillip Gray | 3767 | | | | |
| The MA Period for Reply | ILING DATE of this communication app | ears on the cover sheet with the c | orrespondence address | | | | |
| WHICHEVER - Extensions of time after SIX (6) MON - If NO period for re - Failure to reply will Any reply received | D STATUTORY PERIOD FOR REPLY IS LONGER, FROM THE MAILING DAR is may be available under the provisions of 37 CFR 1.13 THS from the mailing date of this communication. ply is specified above, the maximum statutory period within the set or extended period for reply will, by statute, if by the Office later than three months after the mailing in adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION (6(a). In no event, however, may a reply be tim (ill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | I. nely filed the mailing date of this communication. D (35 U.S.C. § 133). | | | | |
| Status | : | | | | | | |
| 1)⊠ Respons | sive to communication(s) filed on <u>05 No</u> | ovember 2007. | | | | | |
| 2a) ☐ This acti | This action is FINAL . 2b)⊠ This action is non-final. | | | | | | |
| | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | | |
| closed in | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Cla | aims | | | | | | |
| 4)⊠ Claim(s) <u>1-14</u> is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | | |
| | 5) Claim(s) is/are allowed. | | | | | | |
| | Claim(s) <u>1-14</u> is/are rejected. | | | | | | |
| · | is/are objected to. | alastian rasuiramant | | | | | |
| 8) 🖸 Claim(s) | are subject to restriction and/or | election requirement. | • | | | | |
| Application Pape | rs | | | | | | |
| 9) The specification is objected to by the Examiner. | | | | | | | |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. | | | | | | | |
| • • | may not request that any objection to the o | • | · · | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | | |
| Priority under 35 | U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. | | | | | | | |
| | | | | | | | |
| | opies of the certified copies of the prior | | | | | | |
| ар | plication from the International Bureau | (PCT Rule 17.2(a)). | • | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
| | | | | | | | |
| Attachment(s) | | | | | | | |
| 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) | | | | | | | |
| | person's Patent Drawing Review (PTO-948) losure Statement(s) (PTO-1449 or PTO/SB/08) I Date | Paper No(s)/Mail Da 5) Notice of Informal P 6) Other: | ate atent Application (PTO-152) | | | | |
| | | | | | | | |

DETAILED ACTION

This Office Action is in response to applicant's communication of 11/5/2007.

Currently amended claims 1-14 are pending and rejected below.

Response to Arguments

Applicant's arguments filed 11/5/2007 have been fully considered but they are not persuasive.

Applicant argues that the added claim language of "releasably mating" is not disclosed by Neftel.

During examination, claim limitations are to be given their broadest reasonable reading. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989); In re Prater, 415 F.2d 1393, 1404-1405, 162 USPQ 541, 550-51 (CCPA 1969). When given the broadest reasonable reading the claims, as currently written, do not overcome the prior art of record, as pointed out above. It is examiners position that the Neftel first axial end does "releasably" mate with a blunt end of a syringe needle. Examiner is reading the term "releasably" in a broad sense of to free from something. As shown in multiple embodiments of Neftel the open axial end would be relasably mated with a blunt end of the needle. Concerning the amendments to claim 7 see figure 3-4 and 8-14.

The elements disclosed in Neftel are fully capable of satisfying all structural, functional, spatial, and operational limitations in the amended claims, as currently written, and the rejection is made and proper. See rejection discussion below.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "bell shaped" in claim 7 is a relative term which renders the claim indefinite. The term "bell" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Examiner is unsure of the exact design or spatial perameters of a "bell shaped" mating member.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States

Claims 1-8, 10, and 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Neftel et al. (U.S. Patent Number 5,827,262). Neftel discloses a syringe device for mixing two compounds (see figures 1-18b, specifically 12-18b). Neftel discloses a syringe (12), sealed vial (10) safety device forming a fluid coupling (14)

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between, a sliding joint (see element at 218 or 66), and a pointed end/blunt needle (34). Further the tubular connector (14) has an open-ended cavity (210), adapted to receive a flange (18) of a vial (10) with stopper, and at least one non-releasable spring clip member (element near 212) which snaps against the vial when it is cammed under and past the spring clip (see figure 12).

The Neftel syringe device is fully capable of satisfying all functional, structural, and spatial claim language limitations. The Neftel device has a sliding joint fully capable of being adapted to releasably engage at least a releasable needle receiver on a distal end from the sliding join after fluid coupling with the vial through the passageway of the sliding joint without removal of the sliding joint from the tubular connector and without the needle. The needle of Neftel can be non-releasably captured in the tubular connector with the sliding joint, and the sliding joint and needle receiver is configured to releasably mate with the blunt mounting end of the enclosed needle, along with the needle mount (see paragraphs at columns 4-17)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9, 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neftel. Neftel discloses the claimed invention except for packaging together in a sealed sterile packaging. It would have been obvious to one having ordinary skill in the art at the time the invention was made to packaging the components together in a sealed sterile packaging since it was known in the art that most medical syringes and components are kept from being contaminated and free from bacteria or other microorganisms by wrapping in sealed sterile packaging like plastic or polymer wrap.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571) 272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PNJ PAG

KEVIN C. SIRMONS SUPERVISORY PATENT EXAMINER

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